REMARKS

Status of Claims

Claims 1-34, 43-45, 51, and 55 stand rejected as allegedly obvious under 35 U.S.C. § 103(a) by U.S. Patent No. 6,251,407 to Ganne ("Ganne") in view of the Barnett et al. article reproduced in Vaccine, Vol. 16, No. 7, pp. 746-754 (1998) ("Barnett article" or "Barnett") and U.S. Patent No. 3,269,905 to Damaskus ("Damaskus"). Applicant respectfully submits amendments to claims 1 and 55. No new matter is added.

Interview

Applicant gratefully acknowledges the interview held with the Examiner on December 30, 2008. In the interview, the claims were discussed in view of the cited references. No agreement was reached with regard to the claims.

Reply to Claim Rejections Under 35 U.S.C. § 103(a)

35 U.S.C. § 103(a) states:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-34, 43-45, 51, and 55 stand rejected as allegedly obvious under 35 U.S.C. § 103(a) by U.S. Patent No. 6,251,407 to Ganne ("Ganne") in view of the Barnett article, and U.S. Patent No. 3,269,905 to Damaskus ("Damaskus"). The Patent Office misapprehends the present claims, the cited references, and Applicants' previous arguments. Applicants respectfully traverse this rejection on three grounds. First, applicants urge that there would have been no reason for one of ordinary skill in the art to have combined the teachings of Ganne with those of the secondary references. Secondly, even if one of ordinary skill in the art were to combine the references in the manner suggested by the Patent Office, a composition as claimed would not result.

Finally, even if properly rejected as *prima facie* obvious, applicants urge that the invention nonetheless patentably defines over the applied prior art by virtue of the unexpected results obtained by applicants.

The present invention relates to a composition comprising:

at least one frozen antigenic medium; and

at least one frozen adjuvant;

wherein the composition is in a solid state,

and wherein the at least one frozen antigenic medium and the at least one frozen adjuvant each comprise one or more phases which are distinct from each other; and

wherein the composition would be in the liquid state at a temperature greater than or equal to 4°C.

The present invention is aimed at developing vaccines which can be stored for several years and which are ready for use after thawing.

A New Form of a Known Compound May Be Nonobvious

As an initial matter, applicants note the concern expressed by the Examiner that a new form of a known composition was necessarily viewed as being novel or non-obvious under the statute. To dispel any doubt, applicants refer the Examiner to *In re Berry*, where the Court of Customs and Patent Appeals reversed the rejection of claims directed to crystalline aluminum oxide, or corundum, in the form of fibers. *In re Berry*, 315 F.2d 916, 916 (C.C.P.A. 1963), attached as Exhibit A. The cited reference disclosed a fibrous product of "a mineral of either the silica group, or of the alumina group." *Id.* The court found that the cited reference did not draw fibrous corundum, so that the claims at issue were not anticipated by the cited reference. *Id.* at 918. The court then turned to an analysis of the claims in light of 35 U.S.C. § 103. The court found "that at least some of the properties of appellant's product, e.g., crystalline structure and

melting point, are different from those. . ." of the cited reference. *Id.* The court reversed the rejection of the claims over the cited reference. *Id.*

Claim 1 of the present application, for example, discloses "at least one frozen antigenic medium," and "at least one frozen adjuvant," where "one or more phases which are distinct from each other. . . ." Ganne does not disclose freezing compounds in one or more phases. The specification of the current application discloses that the preparation of a frozen composition in distinct phases may increase long term storage viability. *See*, for example, the experiments beginning on page 21 of the specification. Storage of the composition in phases is a property of the composition that is different from the properties of the emulsified composition of Ganne.

Ganne Does Not Disclose a Motivation to Store the Composition in Frozen Layers

As noted in the Response dated November 21, 2007 to the Office Action mailed May 31, 2007, which is incorporated herein by reference, the primary reference Ganne discloses an emulsion (see col., 3, ll. 45-54), or compositions created by "simple mixing" (see col. 10, ll. 3-6). Ganne does not disclose storage for the composition created, except to state that the composition "must be stable preferably for at least 12 months when it is stored at 4°C." Ganne, col. 3, ll. 59-61. Ganne does not disclose long term storage of the composition, or that the composition of the at least one antigenic medium and the at least one adjuvant may have longer storage capabilities when the composition elements are stored separately. Separation of the antegenic medium and the adjuvant into phases in a solid state is not disclosed or suggested in Ganne. As Ganne does not disclose or suggest freezing compositions at all, it necessarily cannot disclose or suggest separate phases in a solid state.

The Combination of Ganne, Barnett, and Damaskus Does Not Disclose All Elements of the Claims

The secondary references fail to remedy the deficiencies of Ganne. Damaskus discloses a method for producing dry stratiform products. *See* Damaskus, col. 1, ll. 14-17. "This stratiform product can be prepared by forming a plurality of layers of separately frozen matter in stacked relation. The frozen strata can be dehydrated to obtain the multi-layer composition in dry form." Damaskus, col. 2, ll. 16-19. "The lyophilized product obtained in this process can be reconstituted with a liquid vehicle to produce a composition suitable for medical purposes." Damaskus, col. 3, ll. 28-31. Damaskus thus appears to disclose a method for producing dry stratified products. Freezing strata appears to be required only to stack the strata in order to lyophilize the layers and create a dry stratified product. Damaskus discloses layering frozen strata as an intermediate product (see col. 2, ll. 16-20), however the intermediate product is dehydrated to form a final composition in **dry** form (see col. 2, ll. 18-20; col. 2, ll. 26-27; col. 1; ll. 14-17 ("This invention relates to . . . stratiform products which may be obtained as a package containing a plurality of strata of **dry** matter in stacked relation"); see also Title).

Two things should be immediately apparent. First, there would be no reason for one of ordinary skill in the art to combine the teachings of Ganne and Damaskus. Damaskus seeks a dehydrated, freeze-dried product. One example in Damaskus discloses a preparation of an anti-anemia pharmaceutical package of "individual layers of vitamin B12, an anti-anemia liver concentrate and folic acid *in the lyophilized state.*" Damaskus, col. 2, ll. 5-7 (emphasis added). The examples in Damaskus all include the ultimate freeze-drying of the stratiform products, which is consistent with the title "Dry Stratiform Products and Methods of Producing Same." Ganne, in contrast, does not disclose that the therapeutic compositions should be freeze dried, or that such a product would be desirable. Ganne also does not disclose that freezing the product is desirable. It would not be evident to one of ordinary skill in the art to take a patent directed to

"dry stratiform products," and combine the teachings of Damaskus with the therapeutic composition of Ganne.

The second thing which should be apparent is that even if one of ordinary skill in the art were to combine the teachings of Ganne with Damaskus, a product as claimed would not result. Rather, the application of the teachings of Damaskus, which, as described more fully above, teaches a "dry stratiform product," to the therapeutic composition of Ganne would result in a freeze-dried stratiform product of the therapeutic composition. Such a combination would not disclose at least "at least one frozen antigenic medium; and at least one frozen adjuvant. . ." as disclosed in claim 1, and "freezing at least one antigenic medium into a solid state, . . . and freezing the at least one adjuvant into a solid state. . ." as disclosed in claim 55.

The Barnett article does not overcome the deficiencies enunciated above with respect to Ganne and Damaskus. As discussed in the May 21, 2008 response, the Barnett article discloses an examination of "[t]he protective ability of two novel oil-based FMD vaccines in pigs." Barnett, abstract. The compound(s) used in Barnett are markedly distinct from the compounds disclosed in the present application. The Examiner relies on Barnett for the proposition that "concentrated stocks of vital antigen are stable for years when frozen. . . ." February 21, 2008 Office Action, page 2. Barnett discloses that, to create an "emergency ring-vaccination," "many FMD-free states have access to FMD vaccine banks, which primarily store concentrated, inactivated FMDV antigens at ultralow temperatures." Barnett, p. 746, col. 2. The antigens may be used to create vaccines; the vaccines themselves are not stored in the FMD vaccine bank. Barnett does not disclose or suggest the desirability to freeze a solid state composition, where the "one or more phases [] are distinct from each other." Barnett only discloses that frozen antigen may be stockpiled to later use to make vaccine.

In contrast, independent claims 1 and 55 disclose a "solid state" composition, where the "one or more phases [] are distinct from each other." Neither Ganne, Damaskus, nor Barnett, alone or in combination, discloses a frozen, solid state composition, where the "one or more phases [] are distinct from each other." Ganne

does not suggest that it is desirable to freeze the composition, Damaskus does not fairly suggest a frozen combination of strata over a dry combination of strata, and Barnett discloses only freezing an antigen, to later thaw and make vaccine. There is no suggestion, explicitly or implicitly, of the desirability of having separate solid antigenic medium and adjuvant phases in a single composition wherein the composition would be in a liquid state at temperature greater than or equal to 4°C, as recited in the present claims. As none of the cited references, alone or in combination, suggest the desirability of their combination, explicitly or implicitly, there is no motivation to combine the references. The combination of references is improper and should be withdrawn.

Moreover, even when combined, the teachings of the cited references are deficient. The combination of the teachings would not result in the claimed multi-phase composition wherein at least one antigenic medium and the at least one adjuvant each comprise one or more phases which are distinct from each other and wherein the composition would be in the liquid state at a temperature is greater than or equal to 4°C, as recited in the claims. Ganne, for example, does not disclose that the composition of the at least one antigenic medium and the at least one adjuvant may have long term storage problems. Although the tendency to resort to "hindsight" in examining an application is often difficult to avoid, impermissible hindsight must be avoided and the legal conclusion must be based on facts gleaned from the prior art. MPEP § 2142. Applicant respectfully submits that independent claims 1 and 55 are therefore allowable.

Finally, even if it were *prima facie* obvious to combine the applied prior art in the manner suggested by the Patent Office, applicants note that the claimed composition is non-obvious by virtue of the unexpected results observed by applicants. For example, as set forth at page 20 of the originally filed application, a vaccine prepared in phases remained active after being stored at -20°C for seven months, while vaccines prepared as an emulsion and stored at the same temperature and for the same duration lost their activity. Pages 21 to 25 of the application also outline trials of the vaccines prepared in phases and vaccines in an emulsion. The trials show that the vaccines prepared in

phases "is more effective than a vaccine composition containing the same constituents but which was stored for the same period and at the same temperature in the form of an emulsion (froze) of the various phases." *See* p. 24. The longer stability at frozen temperatures is an unexpected result of the phase preparation as taught in claims 1 and 55.

Claims 2-34, 43-45, and 51 depend from independent claim 1, and Applicants submit that they are themselves allowable at least because of their dependence from allowable independent claim 1. Applicant therefore respectfully requests that the rejection of claims 1-34, 43-45, 51, and 55 under 35 U.S.C. § 103(a) be withdrawn.

CONCLUSION

An indication of allowance of all claims is respectfully solicited. Early notification of a favorable consideration is respectfully requested. In the event any issues remain, Applicants would appreciate the courtesy of a telephone call to their counsel to resolve such issues and place all claims in condition for allowance.

Applicants respectfully request a 2-month extension of time under 37 C.F.R. § 1.136(a) for responding to the Office Action mailed on September 5, 2008, in the above-captioned patent application. Accordingly, it is respectfully requested that the time for response be extended up to and including February 5, 2009. Please charge Deposit Account No. 50-0206 the amount of $490.00 for the 2-month extension of time fee. The Commissioner is hereby authorized to treat any current or future reply, requiring a petition for an extension of time for its timely submission as incorporating a petition for extension of time for the appropriate length of time. In the event of any variance between the amount enclosed and the fees determined by the U.S. Patent and Trademark Office, please charge or credit any such variance to the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,

HUNTON & WILLIAMS LLP

Dated: Feb 5, 2009 By: _____

Robert M. Schulman
Registration No. 31,196
Jonathan B. Burns
Registration No. 51,515

HUNTON & WILLIAMS
INTELLECTUAL PROPERTY DEPARTMENT
1900 K STREET, NW, SUITE 1200
WASHINGTON, D.C. 20006-1109
(202) 955-1500 (TELEPHONE)
(202) 778-2201 (FACSIMILE)

EXHIBIT A

C

United States Court of Customs and Patent Appeals.
Application of Kenneth L. BERRY.
Patent Appeal No. 6932.

April 25, 1963.

Application, serial No. 696,595, was made for a patent for method of producing fibrous corundum. The Patent Office Board of Appeals rendered a decision affirming the rejection of claims 1 and 2 of the application, and the applicant appealed. The Court of Customs and Patent Appeals, Almond, J., held that claims of the application were improperly denied on ground that the claims were unpatentable over the prior art reference.

Decision of Board reversed.

West Headnotes

Patents 291 ⚿66(1.24)

291 Patents
291II Patentability
291II(D) Anticipation
291k63 Prior Patents
291k66 Operation and Effect
291k66(1.24) k. Process, Method, and Apparatus Claims in General. Most Cited Cases
Claims of application for patent for method of producing fibrous corundum was improperly denied on ground that claims were unpatentable over prior art reference. 35 U.S.C.A. § 103.

***916 *1197** C. Harold Herr, Wilmington, Del. (Frederick Schafer, Washington, D.C., of counsel), for appellant.
Clarence W. Moore, Washington, D.C. (Jack E. Armore, Washington, D.C., of counsel), for Commissioner of Patents.

Before WORLEY, Chief Judge, and RICH, MARTIN, SMITH, and ALMOND, judges.

ALMOND, Judge.
This is an appeal from the Board of Appeals decision affirming the rejection of claims 1 and 2 of appellant's patent application.[FN1]

The invention relates to crystalline aluminum oxide in the form of fibers, filaments and ribbons. The particular form of aluminum oxide in question iscorundum or alpha-alumina. This mineral occurs widely in nature, but not in fibrous form. Appellant has disclosed a patentable method of producing the fibrous corundum,[FN2] and the sole question is whether the corundum product is patentable.

Claim 1 is illustrative and reads as follows:

'Corundum in a form having at least one dimension less than 50 microns and one dimension greater than 50 microns, the average ratio of the longest to the shortest dimension being at least 500:1.'

The Board of Appeals affirmed the finding by the examiner that the product claims are unpatentable over the prior art reference. The reference relied on is:

Roiboul (Great Britain) 165,052 December 28, 1921.

The Roiboul reference shows a fibrous product drawn from a molten pool of 'highly refractory mineral substances, such as alumina and silica.'The reference, in referring to the prior art, points out that others had proposed a wheel or bobbin for drawing out glass threads from molten glass. In addition, Roiboul states, filaments of 'silica, alumina and other refractory minerals' had been made by drawing a molten drop of the mineral carried on the end of a rod, but these filaments were too irregular in diameter and the maximum length was only twenty meters, only half a meter of which was usable. The invention in Roiboul is the combination of a novel crucible of a copending application and a high speed wheel or bobbin to draw fibers 'to 100 kilometres, or more.' The specific composition of the raw materials is not defined, but 'may be a mineral of either the silica ***1198** group, or of the alumina group.'The thread of the final product is said to be amorphous and not crystalline.

****917** The Board of Appeals found 'no patentable distinction between the claimed filaments and those of Roilboul.'They said:

'In our opinion, Roiboul teaches a product having the dimensions set forth in appellant's claims and exhibiting the properties desired of the claimed product. Although Roiboul indicates the alumina filaments not to have crystal structure, and to be amorphous, the remaining description of the product coincides with that of appellant's claimed composition. We note, at this point, the lack of any limitation in the claims that the product be crystalline, and we find no evidence requiring crystalline structure as a prerequisite for the desired properties.'

Appellant argues that the limitation of crystalline is inherent in the claim since the word 'corundum,' by definition, is crystalline alpha-alumina. Moreover, while he considers it redundant, appellant offered to amend the claims to crystalline if the board so desired. A number of textbook references to 'corundum' defining it as crystalline were placed of record in appellant's request for reconsideration by the board. On reconsideration, the board stated that the term 'corundum' does not describe the product 'in such manner as to differentiate over the product actually obtained by Roiboul, even though the latter may be described as being amorphous.'From the opinions of the board, it seems clear that they accept the proposition that alpha-alumina (corundum) is crystalline and not amorphous, as argued by appellant. However, it is not clear whether they affirmed on the basis that Roiboul teaches corundum in spite of what the reference says of crystallinity, or whether the inherent limitation of crystallinity is merely an obvious variation over the amorphous alumina of Roiboul contributing no unobvious properties. The statement by the board that: 'The Roiboul filaments are produced from alumina, fused at high temperatures known to form alpha alumina on solidification.' tends to indicate a belief that Roiboul had a crystalline product without knowing it. The rest of the statements, however, indicate a reliance on the requirement of 35 U.S.C. 103 that the subject matter must be non-obvious though it is not identically disclosed or described in the prior art. The board apparently found the claimed subject matter obvious in the absence of a direct comparison with the products prepared by Roiboul in order to support the 'advantages' attributed to appellant's corundum.

Appellant argues that a direct comparison of the Roiboul alumina with appellant's corundum is impossible because Roiboul did not produce alumina fibers. Appellant submits that the asserted equivalency of silica and alumina is erroneous, and that Roiboul merely prepared silica fibers and incorrectly assumed that alumina fibers could be prepared in the same manner. Fibrous alumina cannot, it is ***1199** argued, be obtained by the method of Roiboul, which requires a glass-forming oxide such as silica in order to be operable. To support this contention, an affidavit by John B. Lambert was incorporated into the record. The affidavit had been submitted in another application not concerned with corundum of its preparation, but the Roiboul reference was part of the subject matter of the affidavit. In referring to the Roiboul reference, the affiant attempted to draw fibers from molten alumina of five different types. Platinum and tungsten wires were dipped into the molten alumina and withdrawn.'In no case was there even a tendency for the melt to draw, and no fibers were obtained.'The explanation given by affiant for this is:

'It is observed that it is obvious to any physical chemist that a material such as an inorganic material with a sharp melting point which readily crystallizes from its melt cannot be drawn to form fibers unless some means to prevent crystallization is found. Glass, for example, can be drawn because additions ****918** are made to silica so that the resulting glass does not have a sharp melting point.'

Though no fibera are formed, the five samples of alumina were 'converted to corundum in every case except one,'[FN3] according to the affidavit.

We are wary of affidavits offered to show that what a patentee states has been done cannot be done. The burden of proving inoperativeness of a patented invention is heavy. However, the affidavit is not offered to prove Roiboul inoperative for all purposes, but merely to prove that Roiboul did not produce fibrous corundum.

It seems clear from the record that Roiboul did not draw fibers of pure corundum. Roiboul did not purport to use corundum, and the affiant Lambert swore that he could not have drawn corundum. The evidence of record indicates that corundum was not used in Roiboul since at the temperatures employed a crystalline product would be obtained, whereas Roiboul specifi-

cally states that the fibers are not crystalline. Since Roiboul refers to prior art methods of drawing alumina fibers, it is clear that the patentee did not purport to be the first. Whether the method of Roiboul is inoperative insofar as alumina is concerned, or whether Roiboul used overbroad language in describing his invention, or whether additions to the alumina were present to broaden the melting temperature range, are questions that we need not decide. We merely decide that Roiboul did not draw fibrous corundum.

We note that the record shows the advance in the state of the art from the of Roiboul, who grouped 'silica, alumina, and other refractory minerals' together, to the time of the affiant Lambert, who ***1200** drew distinctions between alpha-alumina, beta-alumina, gamma-alumina, alumina monohydrate, etc. There is an order of magnitude, so to speak, separating the state of the art at the different times. Accordingly, the affidavit of Lambert is given relatively greater weight than if it were introduced merely to prove inoperativeness of a competing process. This is not to say that the affidavit is not without its drawbacks. We note that its purpose was to compare Roiboul to an entirely different fiber of different chemical composition and structure in a separate application from the one under consideration. We rely on the affidavit only for what is said with regard to the Roiboul reference.

Having found that Roiboul does not produce fibrous corundum, we must determine whether it is obvious to produce it under 35 U.S.C. § 103. There is nothing in the record to indicate that anyone had ever made fibrous corundum before appellant or had described how to make it. The worker having ordinary skill in the art knew nothing of fibrous corundum, so we cannot say that it would have been obvious to him to make corundum in the novel form.

The board stated that the 'advantages' of fibrous corundum were argumentative and not supported by a direct comparison with the prior art. Even if there were no 'advantages' in using fibrous corundum for the fibers of Roiboul, we do not believe that fibrous corundum is obvious to the worker having ordinary skill in the art. Moreover, the record does support appellant's contention that fibrous corundum may be used for filtering molten metals at 1500 degrees C., whereas Roiboul states that his material 'becomes pasty' at that temperature. It seems clear that at least some of the properties of appellant's product, e.g., crystalline structure and melting point, are different from those of Roiboul's product. Fibrous corundum is not obvious over the fibers of the prior art reference to Roiboul.

Accordingly, the decision of the Board of Appeals is reversed.

Reversed.

FN1. Serial No. 696,595, filed November 15, 1957, for 'Fibrous Corundum and its Preparation.'

FN2. Method claims 4 to 8 are allowed.

FN3. Beta-alumina, which is not pure aluminum oxide, was said to result from one sample.

Cust. & Pat.App. 1963.
Application of Berry
50 C.C.P.A. 1196, 315 F.2d 916, 137 U.S.P.Q. 353

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